CLAIMS

What is claimed is:

1. A detection method performed on a maternal serum or plasma sample from a pregnant female, which method comprises detecting the presence of a nucleic acid of fetal origin in the sample.

2. The method according to claim 1, comprising amplifying the fetal nucleic acid to enable detection.

3. The method according to claim 1, wherein the fetal nucleic acid is amplified by the polymerase chain reaction.

4. The method according to claim 2, wherein at least one fetal sequence specific oligonucleotide primer is used in the amplification.

5. The method according to claim 1, wherein the fetal nucleic acid is detected by means of a sequence specific probe.

6. The method according claim 1, wherein the presence of a fetal nucleic acid sequence from the Y chromosome is detected.

7. The method according to claim 6, wherein the Y chromosome sequence is from the DYS14 locus.

8. The method according to claim 6, wherein the Y chromosome sequence is from the SRY gene.

9. The method according to claim 1, wherein the presence of a fetal nucleic acid from a paternally-inherited non-Y chromosome is detected.

10. The method according to claim 9, wherein the non-Y sequence is a blood group antigen gene.

11. The method according to claim 10, wherein the blood group antigen is the Rhesus D gene.

12. The method according to claim 9, wherein the non-Y sequence is a gene which confers a disease phenotype in the fetus.

13. The method according to claim 12, wherein the gene is the Rhesus D gene.

14. The method according to claim 9, for Rhesus D genotyping a fetus in a Rhesus D negative mother.

15. The method according to claim 6, for determining the sex of the fetus.

16. The method according to claim 6, which comprises determining the concentration of the fetal nucleic acid sequence in the maternal serum or plasma.

17. The method according to claim 16, wherein the determination of the concentration of fetal nucleic acid sequence in the maternal serum or plasma is by quantitative PCR.

18. The method according to claim 16, for the detection of a maternal or fetal condition in which the level of fetal DNA in the maternal serum or plasma is higher or lower than normal.

19. The method according to claim 16, wherein the pattern of variation of fetal DNA concentration in the maternal serum or plasma at particular stages of gestation is different from normal.

20. The method according to claim 16, for detection of pre-eclampsia.

21. The method according to claim 16, for detection of a fetal chromosomal aneuploidy.

22. The method according to claim 1, wherein the sample contains fetal DNA at a fractional concentration of total DNA of at least about 0.14%, without subjecting it to a fetal DNA enrichment step.

23. The method according to claim 22, wherein the fractional concentration of fetal DNA is at least about 0.39%.

24. A method of performing a prenatal diagnosis, which method comprises the steps of:

(i) providing a maternal blood sample;

(ii) separating the sample into a cellular and a non-cellular fraction;

(iii) detecting the presence of a nucleic acid of fetal origin in the non-cellular fraction according to the method of claim 1;

(iv) providing a diagnosis based on the presence and/or quantity and/or sequence of the fetal nucleic acid.

25. The method according to claim 24, wherein the non-cellular fraction as used in step (iii) is a plasma fraction.

26. A method according to claim 24, including performing the further step of allowing clotting in the maternal sample and using the resulting serum in step (iii).

27. A method of performing a prenatal diagnosis on a maternal blood sample, which method comprises removing all or substantially all nucleated and anucleated cell populations from the blood sample and subjecting the remaining fluid to a test for fetal nucleic acid indicative of a maternal or fetal condition or characteristic.

28. A method of performing a prenatal diagnosis on a maternal blood sample, which method comprises obtaining a non-cellular fraction of the blood sample and performing nucleic acid analysis on the fraction.

29. A method of non-invasive prenatal diagnosis of maternal and fetal conditions comprising:

obtaining maternal serum or plasma from a sample of a pregnant female's blood and detecting the amount of fetal nucleic acid within the serum or plasma.

30. A method according to claim 29 wherein serum or plasma is obtained from multiple blood samples of the same pregnant female taken at different times and the quantity

of fetal nucleic acid contained within the serum or plasma from the different blood samples is compared to diagnose pre-eclampsia.

31. A method of non-invasive prenatal diagnosis for determining maternal or fetal conditions comprising:

obtaining plasma or serum from a sample of a pregnant female's blood, detecting fetal nucleic acid within the serum or plasma and determining the presence or absence of one or more selected nucleic acid sequences in the detected fetal nucleic acid.

32. A method according to claim 31 wherein the presence or absence of a Y chromosome sequence is detected to determine fetal sex.